K112759

OCT 18 2011

Atlas Spine, Inc.
Special 510(k) Premarket Notification: Atlas Spine Pedicle Screw System

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510(k) SUMMARY

Manufacturer:	Atlas Spine, Inc.
Address:	1555 Jupiter Park Drive, Suite #4 Jupiter, FL 33458
Telephone:	561-741-1108
Fax:	561-741-1870
Establishment Reg. No.	3003855635
Official Correspondent:	Thomas G. Smith
Title:	Manager, Regulatory Affairs & Quality Assurance
Telephone:	561-354-4318
Date Prepared:	September 19, 2011
Device Classification Name:	Spinal pedicle fixation orthosis
Trade/Proprietary Name:	Apelo™ Pedicle Screw System
Common Name:	Pedicle screw spinal system
Classification:	Class III per 21 CFR §888.3070
Product Code:	MNI, MNH, and NKB
Classification Panel:	Orthopedic and Rehabilitation Devices Panel
Predicate Devices:	Apelo™ Pedicle Screw System Atlas Spine, Inc. K072426, K110842 Coral™ Spinal System Theken Spine, LLC K041592, K081414

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Intended Use:

The Apelo™ Pedicle Screw System is intended for noncervical pedicle fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion.

Device Description:

The subject of this submission is the design of Fixed Length Cross Connectors for the Apelo™ Pedicle Screw System and additional smaller sizes, 20mm through and including 42mm. The Atlas Spine Fixed Length Cross Connectors will provide surgeons additional smaller sizes from which to choose based on the patients' anatomies. The Atlas Spine Fixed Length Cross Connectors will be manufactured from medical grade titanium alloy, Ti-6Al-4V (ELI), in accordance with ASTM F-136.

Equivalence to Marketed Product

Atlas Spine, Inc. has submitted information to demonstrate that, for the purpose of FDA's regulation of medical devices, the Atlas Spine Fixed Length Cross Connectors is substantially equivalent in the intended use, design, materials and functional characteristics compared to the predicate devices.

The subject device similarities include:

- The same indications for use
- The same operating principle
- The same raw materials
- Similar manufacturing environments
- The same packaging configurations
- The same sterilization process
- Implanted using the same surgical techniques and similar equipment types

Conclusion

Provided documentation demonstrates that the Atlas Spine Fixed Length Cross Connectors is substantially equivalent to the aforementioned predicate devices. This conclusion is based on the devices' similarities in indications for use, design, function, materials and mechanical function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Atlas Spine, Inc.
% Mr. Thomas Smith
Manager, Regulatory Affairs & Quality Assurance
1555 Jupiter Park Drive, Suite 4
Jupiter, Florida 33458

OCT 18 2011

Re: K112759
Trade/Device Name: Apelo Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: September 19, 2011
Received: September 22, 2011

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112759

Device Name: Apelo™ Pedicle Screw System

Indications for Use:

The Apelo™ Pedicle Screw System is intended for noncervical pedicle fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K112759